Supreme Court U.S.
FILED
JUL 5 - 2005
OFFICE OF THE CLERK

No. 05-48

IN THE

Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC.,

Petitioner,

v.

PFIZER, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

WILLIAM F. SHEEHAN
GOODWIN PROCTER LLP
901 New York Avenue, N.W.
Washington, DC 20001
(202) 346-4000

THOMAS L. CREEL, P.C.
MARK I. KOFFSKY
GOODWIN PROCTER LLP
599 Lexington Avenue
New York, NY 10022
(212) 813-8800

HENRY C. DINGER, P.C.
Counsel of Record
GOODWIN PROCTER LLP
Exchange Place
Boston, MA 02109
(617) 570-1000

QUESTIONS PRESENTED

Federal law requires pharmaceutical companies to list, for every new drug, all patents that "could reasonably be asserted" against a generic version of the drug. To promote the prompt resolution of disputes concerning such patents — and thereby accelerate the introduction of generic drugs — Congress in 2003 specifically authorized generic drug companies to bring an action for a declaratory judgment that a listed patent was invalid or not infringed, 21 U.S.C. § 355(j)(5)(C)(i)(II), and directed federal courts to exercise subject matter jurisdiction over such actions "to the extent consistent with the Constitution," 35 U.S.C. § 271(e)(5). The questions presented are:

1. Whether the court below erred in holding, contrary to the rulings of other circuit courts and to this Court's decision in *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227 (1937), that a generic company can establish jurisdiction under Article III in declaratory judgment actions *only* by proving that it faces "a reasonable apprehension of imminent litigation" for patent infringement.

2. Whether the court below erred in holding that Congress intended to require such a reasonable apprehension of imminent litigation as a condition to the exercise of jurisdiction in declaratory judgment actions under 21 U.S.C. § 355(j)(5)(C)(i)(II) and 35 U.S.C. § 271(e)(5), even though that requirement is contrary to the plain meaning of these statutes and would preclude such actions in precisely the circumstances in which Congress intended to authorize them, *i.e.*, when, by delaying the commencement of infringement litigation, the patentee can effectively extend the term of pharmaceutical patents and delay competition from generic drugs.

LIST OF PARTIES

All parties in the proceedings below are listed in the caption to this petition.

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

The parent corporations of petitioner, Teva Pharmaceuticals USA, Inc., are: Orvet UK Ltd., Teva Pharmaceuticals Europe, and Teva Pharmaceutical Industries Ltd. Teva Pharmaceutical Industries Ltd. is a publicly held company that owns 10% or more of the petitioner's stock.

TABLE OF CONTENTS

QUESTIONS PRESENTED i

LIST OF PARTIES ii

RULE 29.6 CORPORATE DISCLOSURE STATEMENT ii

TABLE OF CONTENTS iii

TABLE OF AUTHORITIES vi

OPINIONS BELOW 1

JURISDICTION 1

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED 1

INTRODUCTION 3

STATEMENT OF THE CASE 5

Teva's Abbreviated New Drug Application 5

Pfizer's Infringement Claim Against IVAX 7

The District Court Decision 8

The Federal Circuit Panel Decision 9

Denial of Rehearing and Rehearing En Banc 11

REASONS FOR GRANTING THE PETITION 12

I. The Decision Below Gravely Undermines Congressional Efforts to Reduce the Cost of Prescription Drugs. 14

II. The Decision Below Purports to Resolve an Important Federal Question in a Manner that Conflicts with the Decisions of this Court and those of other Federal Circuit Courts. 20

III. The Decision Below will Impose an Unjustified and Unprecedented Limitation on Subject Matter Jurisdiction in Patent Cases throughout the Country that Congress will be Unable to Remedy. 25

CONCLUSION 26

APPENDICES

Appendix A — Opinion of the United States Court of Appeals for the Federal Circuit Filed January 21, 2005..... 1a
Dissenting Opinion of Judge Mayer..... 27a

Appendix B — Opinion of the United States District Court for the District of Massachusetts Granting Defendant's Motion to Dismiss Filed December 8, 2003..... 37a

Appendix C — Opinion of the United States Court of Appeals for the Federal Circuit Denying Petition for Panel Rehearing and Rehearing En Banc Filed April 4, 2005..... 48a
Dissenting Opinion of Judge Gajarsa..... 50a
Dissenting Opinion of Judge Dyk 60a

Appendix D — 21 U.S.C. § 355(j)(5)(C) 67a

Appendix E — 149 Cong. Rec. S15884-86 (Nov. 25, 2003) 71a

Appendix F — H.R. Conf. Rep. No. 108-391, at 836 (2003) 82a

TABLE OF AUTHORITIES

Cases

Aetna Life Ins. Co. v. Haworth,
300 U.S. 227 (1937) ..... i, 11, 21, 22

Asarco, Inc. v. Kadish,
490 U.S. 605 (1989) 22

Ass'n of Data Processing Serv. Orgs. v. Camp,
397 U.S. 150 (1970) 23

Bennett v. Spear,
520 U.S. 154 (1997) 21

BP Chems., Ltd. v. Union Carbide Corp.,
4 F.3d 975 (Fed. Cir. 1993) 17

Bresnick v. United States Vitamin Corp.,
139 F.2d 239 (2d Cir. 1943) 20

Calderon v. Ashmus,
523 U.S. 740 (1998) 11

Cardinal Chemical Co. v. Morton Int'l, Inc.,
508 U.S. 83 (1993) 13, 20

Clair v. Kastar,
148 F.2d 644 (2d Cir. 1945) 20

Dewey & Alma Chem. Co. v. American Anode, Inc.,
137 F.2d 68 (3d Cir. 1943) 25

Eli Lilly & Co. v. Medtronic, Inc.,
496 U.S. 661 (1990) 3, 6, 8, 14-16

Gen-Probe, Inc. v. Vysis, Inc.,
359 F.3d 1376 (Fed. Cir. 2004) 17

Hal Roach Studios, Inc. v. Richard Feiner & Co.,
896 F.2d 1542 (9th Cir. 1989) 25

Lujan v. Defenders of Wildlife,
504 U.S. 555 (1992) 21

Maryland Cas. Co. v. Pacific Coal & Oil Co.,
312 U.S. 270 ..... 13, 22, 23

Merck KGAA v. Integra Lifesciences I, Ltd.,
545 U.S. ___, 125 S. Ct. 2372 (2005) 15

Minnesota Mining & Mfg. Co. v. Barr Labs.,
289 F.3d 775 (Fed. Cir. 2002) 7, 17

Mova Pharm. Corp. v. Shalala,
140 F.3d 1060 (D.C. Cir. 1998) 17, 18

Sallen v. Corinthians Licenciamentos Ltda,
273 F.3d 14 (1st Cir. 2001) 24

Sankyo Corp. v. Nakamura Trading Corp.,
2005 U.S. App. LEXIS 4339, at *9-*11
(6th Cir. Mar. 15, 2005) 24

Societe de Conditionnement en Aluminium v. Hunter Engineering Co.,
655 F.2d 938 (9th Cir. 1981) 24, 25

Starter Corp. v. Converse, Inc.,
84 F.3d 592 (2d Cir. 1996) 25

Steel Co. v. Citizens for a Better Environment,
523 U.S. 83 (1998) 11

Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.,
2003 U.S. Dist. LEXIS 21940
(D. Mass. Dec. 8, 2003), *aff'd*,
395 F.3d 1324 (Fed. Cir.), *reh'g denied*,
405 F.3d 990 (Fed. Cir. 2005) 1

Warth v. Seldin,
422 U.S. 490 (1975) 21

U.S. Constitution and Statutes

21 U.S.C. § 355(b)(1) 5, 15

21 U.S.C. § 355(j)(2)(A) 6

21 U.S.C. § 355(j)(5)(B) 6, 7, 15

21 U.S.C. § 355(j)(5)(C) ..... i, 2, 9, 18

28 U.S.C. § 1254(1) 1

28 U.S.C. § 1295(a) 26

28 U.S.C. § 1331 8

28 U.S.C. § 1338(a) 8

28 U.S.C. § 2201 ..... 2, 3, 8

35 U.S.C. § 271(e)(1) 15

35 U.S.C. § 271(e)(2) 4, 6, 15

35 U.S.C. § 271(e)(5) ..... i, 2, 9, 18, 21

U.S. Constitution, Art. III, section 2, clause 1 1

Other Authorities

149 Cong. Rec. S15885 (Nov. 25, 2003) 17

Centers for Medicare & Medicaid Services, National Health Expenditures Aggregate Amounts and Average Annual Percent Change, by Type of Expenditure: Selected Calendar Years 1980-2003 14

Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (2002) 14

H.R. Conf. Rep. No. 108-391 (2003) 18

Letter from Douglas Holtz-Eakin, Director Congressional Budget Office to Hon. William M. Thomas, Chairman, House Committee on Ways and Means (Nov. 20, 2003) 19

OPINIONS BELOW

The decision of the United States Court of Appeals for the Federal Circuit (App. 1a-36a) for which review by this Court is sought is reported at 395 F.3d 1324 (Fed. Cir. 2005). The order denying rehearing and rehearing en banc from that decision, together with the opinions dissenting from the denial of rehearing (App. 48a-66a), is reported at 405 F.3d 990 (Fed. Cir. 2005). The decision of the United States District Court for the District of Massachusetts reviewed by the Federal Circuit (App. 37a-47a) is set forth at 2003 U.S. Dist. LEXIS 21940 (D. Mass. Dec. 8, 2003).

JURISDICTION

The judgment of the Federal Circuit was entered on January 21, 2005. App 1a. A timely petition for rehearing and rehearing en banc was denied on April 4, 2005. App. 48a-50a. This Court has jurisdiction to review the judgment of the Federal Circuit under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

U.S. Constitution, Art. III, section 2, clause 1 provides in pertinent part:

> The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority.

Section 505(j)(5)(C)(i)(II) of the Federal Food, Drug, and Cosmetic Act, as added by the Medicare, Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1101(a)(2)(C), 117 Stat. 2451 (2003), 21 U.S.C.A. § 355(j)(5)(C)(i)(II) (West Supp. 2005), reads in part:[1]

> **(C) Civil Action to obtain patent certainty**
>
> * * *
>
> If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the [abbreviated new drug] applicant referred to in such subclause may, in accordance with [28 U.S.C. § 2201], bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval ....

35 U.S.C.A. § 271(e)(5) (West Supp. 2005) (as added by Pub. L. No. 108-173, § 1101(d), 117 Stat. 2457 (2003)) provides:

---

[1] The full text of 21 U.S.C. § 355(j)(5)(C) is set forth at App. 67a-70a.